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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,268	02/11/2002	Tomoya Takahashi	02139.000029	9453

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EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/22/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/049,268	TAKAHASHI ET AL.
	Examiner Vickie Kim	Art Unit 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-49 is/are pending in the application.
 - 4a) Of the above claim(s) 5,6,8-26 and 29-49 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4,7,27 and 28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4&6</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election acknowledged

Applicants affirmation on the election of Group I and of formula III (species), claims 1-4, 7 and 27-28 is acknowledged. Applicant's election was made without traverse. Therefore, restriction requirement deems proper and made FINAL.

Status of Application

Acknowledgement is made of election 05/13/2003.

The claims 1-49 are pending. the elected claims 1-4, 7 and 27-28 are presented for the examination and the non-elected claims 5-6, 8-26, 29-49 are withdrawn from the consideration.

Information Disclosure Statement

Applicant's information disclosure statement received 4/25/02 and 9/26/02(paper no. 4&6) has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Claim Objections

1. Claims 7, 27-28 are objected to because of the following informalities: the instant claims include an unnecessary parenthetical expression in lines 4-6, respectively. Since the definitive sentence included in parenthesis is connected by the proper indicative conjunction(i.e. wherein), it is unnecessary to use parenthesis. Deleting the parenthesis would obviate this objection. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using lysophosphatic acids and phosphatidic acids having the formulas (I)-(III) wherein carbon atoms in fatty acid residues is from 1 to 23, does not reasonably provide enablement for any compounds other than lysophosphatic acids and phosphatidic acids having the formulas (I)-(III) with carbon atoms in fatty acid residues is from 1 to 23. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Nature of the invention: a hair growing agent comprising lysophosphatic acids and phosphatidic acids having the formulas (I)-(III) with carbon atoms in fatty acid residues is from 1 to 23.

Level of ordinary skill in the art.

The level of ordinary skill in the art is high.

Level of predictability in the art.

The unpredictability of the pharmaceutical art is very high. The art pertaining to the physiological and pharmacological activity of a chemical or biological compound is considered to be highly unpredictable.

Amount of direction and guidance provided by the inventor.

The amount of guidance or direction needed to enable the invention is inversely related to the degree of predictability in the art. *In re Fischer*, 839, 166 USPQ 24. Thus, although a single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements, in cases involving unpredictable factors, such as most chemical reactions and physiological activity, more teaching or guidance is required. *In re Fischer* 427 F 2d 839, 166 USPQ 24; *Ex Parte Hitzeman*, 9 USPQ 2d 1823.

The specification provides no guidance, in the way of enablement for any phoaphatidic acid compounds having more than 24 carbon atoms in the fatty acid residue. A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of claims will possess the alleged activity.

Existence of working examples.

As stated above, the specification does not disclose any working examples of any phoaphatidic acid compounds having more than 24 carbon atoms in the fatty acid residue that are used in the treatment of nail infection or any other pathological conditions.

Breadth of claims.

The claims are extremely broad due to the vast number of possible compounds with phosphatidic acid moiety or phosphatidic acid compounds having more than 24 carbon atoms in the fatty acid residue.

Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The quantity of experimentation needed to be performed by one skilled in the art is yet another factor involved in the determining whether "undue experimentation" is required to make and use the instant invention. "The test is not merely quantitative since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." In re Wands, 858 F. 2d 737, 8 USPQ2d 1404(citing In re Angstadt, 537 F.2d 489, 502-04, 190 USPQ 214, 218 (CCPA 1976)). The skilled artisan would have a numerous amount of modifications to perform in order to obtain substituted compounds as claimed. For these reasons, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine all the possible substitution of the alcohols and carboxylic acids that would be enabled in this specification.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed process without undue experimentation, see In re Armbruster 185 USPQ 152 CCPA 1975.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 1 recites the limitation "the fatty acid residue" in 4. There is insufficient antecedent basis for this limitation in the claim. Thus, claim 1 and its dependent claims are properly included in this rejection. Appropriate correction is required.

6. The term "substantially" in claim 2 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For instance, state of the art recognizes the term "substantially" in an amount of about 10% or less. However, it is not clear whether the general interpretation recognized by the artisan should be applied in this case or not. If it is not, it is not clear what applicant's definition is in respect to the term "substantially". Clarification is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1-4, 7, 27-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Bathurst et al(US 6,004,579).

Claims are directed to a hair growing composition comprising one or more members selected from the group consisting of lysophosphatidic acids and phosphatidic acids, as active ingredients.

US'579 teaches a composition comprises lysophosphatidic acids(LPA) and phosphatidic acids (PA), see claims 1. It also teaches the general formula of LPA and PA at column 5, wherein fatty acid residue(i.e. RC(O)O) is the selected from the group consisting of lauryl, myristoyl, palmitoyl, palmitoleyl or oleyl, see column 5, lines 55-65. Furthermore, US'579 teaches that the patented composition is effectively treat baldness or hair loss wherein the composition can be formulated into topical composition, see claims 44-45. At column 11, in line 25-32, the active agent would be included in the composition in a therapeutically effective amount of about 0.001-10%. Since the active agent is mixture where each component has specific weight ratios, for instance, PA(15):PI(15):LPA(10):LPI(4):LPC(8)(see the patented claim 1), one would readily obtain the actual weight content amount of PA and LPA in the patented composition, that are is about 0.00047-4.7%.

All the critical elements are well taught by the cited reference and the claimed subject matter is not patentably distinguished over the prior art of the record.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-4, 7, 27-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. US6562803. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed subject matter is well encompassed by the patented formula(see claims 1-2. When R4 is substituted by CH3 and R3 is substituted by R1 of US'803, the scope of the instant claims would be identical to the scope of the patented claims wherein the preamble (a hair growing agent) indicates that the effective amount of active agent for producing therapeutic effectiveness(hair growing effect) would be inherently featured in about 0.01 to 5%. In any event, Titration of the effective dosage amount to determine the optimum therapeutic effectiveness is considered to be well within the skilled level of the artisan having ordinary skill in the art and thus, obvious absent evidence to the contrary.

Art Unit: 1614

Thus, all the claims are obvious over the patented claims.

Conclusion

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications.. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,
Patent examiner
August 13, 2003
Art unit 1614